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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/755,456	01/05/2001	Frederic Delbac	1566-00	5009

7590 05/02/2003

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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 05/02/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>09/755,456</b>	Applicant(s) <b>Delbac et al</b>
	Examiner <b>Mark Navarro</b>	Art Unit <b>1645</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)  Responsive to communication(s) filed on Feb 27, 2003

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4)  Claim(s) 2, 4, 5, 33, and 34 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 2, 4, 5, 33, and 34 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some\* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)      4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)      5)  Notice of Informal Patent Application (PTO-152)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_      6)  Other: \_\_\_\_\_

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## **DETAILED ACTION**

Applicants amendment filed February 27, 2003 (Paper Number 12) has been received and entered. Claims 1, 3 and 6-32 have been canceled, consequently claims 2, 4-5 and 33-34 are pending in the instant application.

### ***Claim Rejections - 35 USC § 112***

1. The rejection of claims 33-34 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic compositions comprising the purified microsporidian polar tube protein, does not reasonably provide enablement for pharmaceutical/vaccine compositions comprising the purified microsporidian polar tube protein, or pharmaceutical/vaccine compositions comprising a fragment of the polar tube protein is maintained. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants are asserting that while the specification does not contain detailed experiments utilizing human or mammalian subjects for proof of efficacy of the composition utilizable to prevent infections or act as a vaccine, there is nothing particularly unusual about the way in which a pharmaceutical composition capable of preventing infections caused by microsporidians of genus *Encephalitozoon* is used herein. Applicants further assert that protocols for such

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compositions are essentially well known and easily within the skill of one of ordinary skill in the art without undue experimentation.

Applicants arguments have been fully considered but are not found to be fully persuasive.

Applicants arguments are not found to be fully persuasive in view of the teachings of Plotkin *et al.* As set forth previously, it is well recognized in the art that it is unclear whether a single protein derived from a pathogen will elicit protective immunity. Ellis, R.W. (see Chapter 29 of "VACCINES" [Plotkin, S.A *et al.*,(ed.), published by W.B. Saunders Company (Philadelphia) in 1988, especially page 571, 2nd full paragraph] exemplifies this problem in the recitation that "The key to the problem (of vaccine development) is the identification of that protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies ...and thus protect the host against attack by the pathogen." While Applicants isolated protein remains enabled for an immunogenic composition, as shown by Plotkin the generation of a pharmaceutical/vaccine composition is anything but routine as asserted by Applicants.

A vaccine "must by definition trigger an immunoprotective response in the host vaccinated; mere antigenic response is not enough." In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

Since no working examples are set forth in the specification that the claimed polypeptides are useful for vaccination and the art teaches of the unpredictability of using a single antigen for

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vaccination it would be an undue burden and be unpredictable to use the broadly claimed product for vaccination.

For reasons of record in Paper Number 10, as well as the reasons set forth above, this rejection is maintained.

2. The rejection of claim 4 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the recitation of “functionally equivalent derivative thereof.” is withdrawn in view of Applicants amendment.

***Claim Rejections - 35 USC § 102***

*The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:*

*A person shall be entitled to a patent unless -*

*(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.*

3. *The rejection of claims 1, 4, and 33-34 under 35 U.S.C. 102(b) as being anticipated by Keohane et al is withdrawn in view of Applicants amendment.*

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4. The rejection of claims 2, 4-5, and 33-34 under 35 U.S.C. 102(b) as being anticipated by Delbac *et al* is maintained.

Applicants are asserting that Delbac fails to disclose a complete and purified polar tube protein, rather the work carried out according to Delbac provide only a general teaching concerning a polar tube protein of 55 kDa which does not allow one skill in the art to obtain such a protein in complete and purified form. Applicants further assert that the apparent molecular mass and cross reaction are just enough to consider that they are the prior art and the claimed proteins may have some similar epitopes, but not that they are the same proteins. Applicants further direct the Examiners attention to the electrophoresis profiles in the drawings where one band can contain several proteins, and accordingly it would be in error to conclude that the sequence of the protein is inherently that of SEQ ID NO: 1.

Applicants arguments have been fully considered but are not found to be persuasive.

Applicants arguments are not found to be persuasive in view of the disclosure of Delbac *et al.*

Applicants assert that Delbac fails to disclose a complete and purified polar tube protein, rather the work carried out according to Delbac provide only a general teaching concerning a polar tube protein of 55 kDa which does not allow one skill in the art to obtain such a protein in complete and purified form. However, Applicants attention is directed to the left column in which Delbac report that "The 55 kDa polar tube protein was separated by two-dimensional

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electrophoresis and two peptide fragments of 15 and 20 amino acids were sequenced.” Being able to “sequence” the protein required the protein to be “purified.” Furthermore, the full length protein has a molecular weight of 55 kDa, consequently the protein disclosed by Delbac was both full length and purified. Furthermore, Delbac *et al* report the protein to have “395 amino acids.” (Right column). The full length protein of the instant invention just happens to have 395 amino acids. Since the Patent office does not have the facilities for examining and comparing applicants’ product with the product of the prior art reference, the burden is on applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977). This is particularly true given that Frederic Delbac (author of the above cited Delbac *et al* reference) is also named as the inventor of the instantly filed application.

The claims are directed to purified microsporidian polar tube proteins comprising the amino acid sequence of SEQ ID NO: 1.

Delbac *et al* (Journal of Eukaryotic Microbiology Vol 44, No. 6, page 77S, 1997) (IDS ref AR) disclose of the purification of a 55 kDa polar tube protein from the microsporidian species, *Encephalitozoon cuniculi*. Delbac *et al* further set forth of determining the isoelectric point to be about 5. Delbac *et al* further set forth of expressing the protein in *E. coli* and injecting the protein in mice. (See entire article).

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In view that the instantly filed application claims a microsporidian polar tube protein obtained from *Encephalitozoon cuniculi* with a molecular weight of 55 kDa and an isoelectric point of about 5, and that Delbac *et al* set forth of a microsporidian polar tube protein obtained from *Encephalitozoon cuniculi* with a molecular weight of 55 kDa and an isoelectric point of about 5, the disclosure of Delbac *et al* is deemed to anticipate the claimed invention.

It is noted that Delbac *et al* do not characterize the sequence of the isolated protein, however, in view that both the instantly claimed protein and the protein disclosed by Delbac *et al* are:

--obtained from *Encephalitozoon cuniculi*  
are polar tube proteins  
have a molecular weight of 55 kDa  
and an isoelectric point of about 5

the sequence of the protein is deemed to inherently be that of SEQ ID NO: 1.

The following new grounds of rejection are applied to the claims:

***Claim Objections***

5. Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the

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claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 5 recites a protein comprising amino acids 23-395 of SEQ ID NO: 1, however the claim from which it depends already comprises amino acids 1-395 of SEQ ID NO: 1. Consequently, claim 5 no longer limits, but rather broadens the scope of claim 4. Appropriate correction is required.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should be faxed to Group 1645 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.



Mark Navarro

Primary Examiner

May 1, 2003